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**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/921,533	09/02/97	TORMALA	P 2880/27

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WASHINGTON DC 20036

HM12/1016

EXAMINER

CHANNAVAJJALA, L

ART UNIT	PAPER NUMBER
1615	16

DATE MAILED: 10/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/921,533

Applicant(s)

Tormala et al

Examiner

Lakshmi Channavajjala

Group Art Unit

1615



☒ Responsive to communication(s) filed on Aug 15, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Receipt of extension of time, amendment C, dated 8-15-00 and change of address dated 8-24-00 is acknowledged.

The following is the outstanding rejection made in previous office action (dated 4-11-00):

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent No. 5084051 to Tormala et al (hereafter '051).

'051 teaches surgical biocomposite material suitable for bone surgical applications comprising a polymeric reinforcing element and bioceramic element, wherein the polymeric reinforcing element could be a mixture of polymers or polymer and porous or non porous bioceramic material (abstract, lines bridging cols. 1 and 2; col. 3, lines 14-53; col. 4, lines 19-68, col 5-6, col. 8, lines 61-68, col. 9-10). The reinforcing polymer is in the form of reinforcing fibers resulting composite has good mechanical strength and integrity and is easy to handle. '051 teaches the various methods of manufacturing the composite as claimed in the instant invention and the addition of additives which facilitate bone growth and /or antibiotics in the composite material.

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Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051).

'051 discussed above does not teach the claimed diameter of the reinforcing elements. However, '051 teaches the reinforcing elements to give the required strength to the biocomposite, while at the same time allowing for maximum in growth of bone tissue (col. 7). Therefore, it is the position of the examiner that optimizing the parameters such as diameter or thickness of the fibers of reinforcing polymer as well as the size of the bioceramic particles is well within the scope of ordinary skill in the art, such that the composite allows for the in growth of the bone and fibers impart good mechanical strength to the composite.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051) as applied to claims 1-8 and 11-22 above, and further in view of Bonfield et al.

Tormala discussed above does not teach the volume fraction of bioceramic as claimed in the instant invention. Bonfield et al teaches bone composites containing hydroxyapatite and polyethylene composites of 0.3 to 0.5 volume fraction, which imparts fracture toughness to the

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composite. Accordingly, it would have been obvious for one of a skilled artisan to machine the bone composites having a volume fraction which increases the toughness and strength of the composite and have comparable mechanical properties with that of the bone.

Response to Arguments

6. Applicant's arguments filed 8-15-00 have been fully considered but they are not persuasive.

USPN 5,084,051 to Tormala et al ('051):

Applicants submit that patent '051 is aimed at strengthening the biocomposite material made of brittle bioceramic, as a consequence of the strong and tough reinforcing elements. Accordingly, applicants argue that '051 does not anticipate or suggest the instant ductile biocomposite material. This argument is not persuasive because, applicants themselves state that in the instant case "reinforcement changes the behaviour of material from brittle to ductile and thus makes the device more reliable under load" [emphasis added], i.e., the instant invention is also aimed at protecting the brittle bioceramic material by reinforcing with polymers. Thus, both instant case and '051 are directed to the same invention and therefore the biocomposites of '051 are rendered ductile because of the reinforcing elements. Moreover, from the teachings of '051 that reinforcing polymers strengthen the biocomposite, it would have been within the scope of a skilled artisan as to optimize the amount of reinforcement so as to obtain a biocomposite which is strong enough to protect the composite from being brittle and at the same

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time have desired ductility. Further, the bioceramic of '051 supports the bony on growth as required by the claims.

With respect to the teachings of Bonfield et al, applicants urge that the reference merely discloses volume fraction, but does not teach present claims. However, this argument is not persuasive because, Bonfield teaches hydroxyapatite reinforced composite materials and their role in increasing the bone toughness, which is the same field of endeavor as that of Tormala ('051). Accordingly, it is the position of the examiner that it would have been obvious for a skilled artisan at the time of instant invention to prepare bone composites with optimum volume fraction which renders the biocomposite tough and strength and at the same time have desired ductility.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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For the above mentioned reasons, the rejection is deemed to be proper.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438 and E-mail address is lakshmi.channavajjala@uspto.gov. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-308-1235).



Lakshmi S. Channavajjala
10/12/2000

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SUPERVISORY PATENT EXAMINER
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